K010509

Section E. 510 (k) Summary Of Safety And Effectiveness

(The following information is in conformance with 21 CFR 807.92.)

Date Prepared February 15, 2001

Establishment Name and Registration number of submitter

Name: GE/SMV America
8380 Darrow Road
Twinsburg, Ohio 44087
Registration number: 1528274
Contact: Paula McLean

Device name and classification

Classification Code: 90 KPS
Panel Identification: Radiology
Proprietary Name: Cedars-Sinai BPGS and MoCo
Common Name: Gamma Camera System
Classification Name: System, Emission Computed Tomography
Classification Class: Class II Product

Reason for submission New device.

Predicate device ELGEMS eNTEGRA K003264
ADAC AutoSPECT K992317
Siemens E.CAM K992731

Device Description

The BPGS and MoCo programs are independent, standalone software applications developed by Cedars-Sinai Medical Center for the automatic processing and analysis of nuclear medicine SPECT data. BPGS quantifies gated blood pool (technetium-labeled red blood cells) data. MoCo corrects for patient motion in SPECT raw data. The programs will run on the Vision® (K912573) processing and display workstation for nuclear medicine images.

Intended Use

The Cedars-Sinai BPGS program is intended for use in the quantification of right and left ventricular volumes and ejection fraction from cardiac SPECT gated blood pool data acquired on a nuclear medicine gamma camera system. The Cedars-Sinai MoCo program is intended for use in correcting patient motion artifact in SPECT data acquired on a nuclear medicine gamma camera system.

Substantial Equivalency

The BPGS and MoCo software applications are substantially equivalent in terms of safety and effectiveness to the above mentioned legally marketed predicate devices. The

predicate devices are the same software applications developed by Cedars-Sinai Medical Center as the BPGS and MoCo programs described herein. The intended use and technological characteristics are identical.

Testing

Testing was conducted to demonstrate that each software application functioned as per its specifications. All tests passed with the actual results matching the expected results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 7 2001

Ms. Paula McLean
Applications Manager
SMV America
8380 Darrow Road
TWINSBURG OH 44087

Re: K010509
Cedars-Sinai BPGS and Moco
Dated: February 15, 2001
Received: February 21, 2001
Regulatory Class: II
21 CFR §892.1200/Procode: 90 KPS

Dear Ms. McLean:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Section F. Indications for Use Form

510(k) Number (if known): K010509

Device Name: Cedars-Sinai BPGS and MoCo Software Programs

Indications For Use:

The Cedars-Sinai BPGS program is intended for use in the quantification of right and left ventricular volumes and ejection fraction from cardiac SPECT gated blood pool data acquired on a nuclear medicine gamma camera system. The Cedars-Sinai MoCo program is intended for use in correcting patient motion artifact in SPECT data acquired on a nuclear medicine gamma camera system.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device (ODE)

David C. Seyman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010509

Prescription Use ✓

(Optional Format 3-10-98)